No. 83-1925

In the Supreme Court of the United States

OCTOBER TERM 1984

HILLSBOROUGH COUNTY, FLORIDA, ET AL.,
APPELLANTS

v.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

APPELLANT'S BRIEF ON THE MERITS

JOE HORN MOUNT
Counsel of Record
Hillsborough County Attorney
P.O. Box 1110
Tampa, Florida 33601
(813) 272-5670

EMELINE C. ACTON
Assistant Hillsborough
County Attorney

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QUESTION PRESENTED

Whether Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder regulating collection of blood plasma from paid donors are pre-empted by the federal regulatory scheme establishing standards and procedures for the collection and manufacture of plasma.

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OPINIONS BELOW

The opinion (JA 40-46)[1] and final judgment (JA 47) of the United States District Court for the Middle District of Florida, William J. Castagna, J., are not reported. The opinion (JA 48-59) of the United States Court of Appeals for the Eleventh Circuit is reported at 722 F.2d 1526. The final judgment (JA 60) is not reported.

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[1]References to the Joint Appendix are indicated by (JA), the Jurisictional Statement Appendix by (JSA) , the Record by (R) and the Transcript by (TR).

JURISDICTION

The United States Court of Appeals for the Eleventh Circuit declared on January 16, 1984, that Hillsborough County Ordinances 80-11 and 80-12 and the implementing rules and regulations are pre-empted by the federal scheme regulating plasma. After the Eleventh Circuit denied Hillsborough County's Petition for Rehearing on February 23, 1984 (JSA 22-26), the County filed its Notice of Appeal to the United States Supreme Court on April 20, 1984 (JSA 27). The jurisdiction of this Court is invoked under 28 U.S.C. §1254(2), which provides for a direct appeal to the United States Supreme Court from a decision of a federal court holding a state statute[2] to be unconstitutional. This Court noted probable jurisdiction on January 14, 1985.

CONSITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding. United States Constitution, Article 6, Clause 2.

2. 21 C.F.R. §§600.3 - 680.26 (1983).

[2]The United States Supreme Court has held that, for purposes of invoking the jurisdiction of the United States Supreme Court under 28 U.S.C. §1254(2), local ordinances are treated as state statutes, *City of New Orleans v. Dukes*, 427 U.S. 297, 96 S.Ct. 2513 (1976).

3. Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder (JA 21-34).

STATEMENT OF THE CASE

Automated Medical Laboratories, Inc. [hereinafter cited as AML], which operates a plasma collection center known as Tampa Plasma Center [hereinafter cited as TPC] in Hillsborough County, Florida, filed a complaint in the U.S. Court for the Middle District of Florida against Hillsborough County, Florida [hereinafter referred to as County] and the Hillsborough County Health Department challenging the constitutionality of Hillsborough County Ordinances 80-11 and 80-12 and the implementing rules and regulations. The first count alleged that the federal government had preempted the area of plasma collection by issuing the regulations contained in 21 C.F.R. §§600.3-680.26 (1983). Following a non-jury trial, United States District Court Judge William J. Castagna rejected all of AML's constitutional attacks on the local legislation, including AML's federal preemption attack, except for the claim that §7 of Ordinance 80-12 and §4 of the rules and regulations requiring a breathanalysis test imposed an impermissable burden on interstate commerce (JA 46, 47).

AML appealed the Judgment of the District Court upholding the validity of the local legislation to the Eleventh Circuit (R 51). The County cross-appealed that portion of the Judgment which held that §7 of Ordinance 80-12 and §4 of the rules and regulations were invalid (R 55).

In its Opinion (JA 48-59) entered on January 16, 1984, the Eleventh Circuit Court of Appeals held that though no express preemption existed, the County ordinances and

regulations were implicitly pre-empted by federal regulations because of their pervasiveness, because of the dominant federal interest in the field and because of a serious danger of conflict between the local and federal regulations.

As a result of this holding, the Eleventh Circuit Court declined to reach any of the other issues raised on appeal. Further, the Court failed to address the point raised by Hillsborough County in its cross-appeal.

Accordingly, the District Court's judgment finding §7 of Ordinance 80-12 and §4 of the County rules and regulations invalid was affirmed, and the Judgment finding the remaining sections of the County ordinances and rules and regulations valid was reversed by the Eleventh Circuit Court of Appeals (JA 60).

SUMMARY OF ARGUMENT

I. Although federal regulations can pre-empt local legislation involving the public health, the administrator must clearly intend such preemption.

II. In the area of plasma regulation, the administrator has stated an intent *not* to pre-empt local law. Other comments from the FDA, as well as their representatives' testimony at trial, indicate that a cooperative approach to plasma regulation between the FDA and state and local governments is the goal of the federal government. Additionally, the local government's main concern of vendor protection is different than that of the federal government which is primarily concerned with protection of plasma.

III. Even if this goal of cooperation and intent not to pre-empt are discounted, the local legislation is not otherwise implicitly pre-empted by the federal regulations.

While the local legislation does provide the four additional vendor protections of county-wide registration, pre-testing for hepatitis, local inspection and breathalyzer testing not found in the federal regulations, none of these provisions conflict with federal law.

The Solicitor General's claim that the pre-test for hepatitis prior to the bleeding of a vendor conflicts with the federal exception allowing for the bleeding of a vendor for manufacture of the hepatitis vaccine is unfounded in that the local legislation includes the federal exception and that the pre-test for hepatitis is not the same as the test for the ingredient in the hepatitis vaccine.

IV. The Eleventh Circuit's ruling that the federal regulations implicitly pre-empt the local legislation due to the federal scheme's pervasiveness and the dominance of federal interest is unsupported by the law and the record. Mere comprehensiveness cannot imply preemption. Likewise federal uniform standards cannot imply exclusivity in the area of plasma vendor protections.

ARGUMENT

I. INTRODUCTION TO PRE-EMPTION PRINCIPLES.

A determination of whether federal law pre-empts state law begins with an examination of the federal law itself. If Congress has expressed a clear intent to pre-empt state law, the state law must yield to that intent. *Jones v. Rath Packing Co.*, 430 U.S. 519, 97 S.Ct. 1305 (1977).[1]

[1] *See, also, Smith v. Pingree*, 651 F. 2d 1021 (5th Cir. 1981) (Unit B). The pre-emptory language from laws under review in the *Jones* and *Smith* cases are, respectively, as follows: "Marking, labeling, packaging, or ingredient requirements in addition to, or different than those made under this Act may not be imposed by any state," *Jones*

Absent an express statement, an implicit intent to pre-empt may be attributed to Congress where: it has left no room for supplementary laws, compliance with both federal and state law is impossible, or the state law stands as an obstacle to congressional purpose and objectives. *Capital Cities Cable, Inc. v. Crisp*, 104 S.Ct. 2694, 2700 (1984).

A presumption against implicit federal preemption exists where the state legislation deals with the health and welfare of its citizenry.[2]

Although federal regulations may pre-empt state law just as federal statutes can, the pre-emption analysis shifts its focus. Where Congress has given an administrator the authority to promulgate regulations, whether those regulations pre-empt state law depends, not upon express congressional authorization, but upon whether the administrator intended to pre-empt state law. If such an intention

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1 Con't.
at 529, 97 S.Ct. 1312 (1977); "[N]o state . . . may establish . . . with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under this statute," *Smith*, 651 F. 2d at 1022 (5th Cir. 1981) (Unit B). In spite of this language in *Smith*, the Fifth Circuit held that Florida law was *not* pre-empted.

[2]*See, e.g., Head v. New Mexico Board of Examiners in Optometry*, 374 U.S. 424, 428, 83 S.Ct. 1759, 1762 (1963), " . . . the statute here involved is a measure directly addressed to protection of the public health, and the statute thus falls within the most traditional concept of what is compendiously known as the police power. [footnote omitted] The legitimacy of state legislation in this precise area has been expressly established. [Citation omitted]."; and *Jones v. Rath Packing Co., supra* at 525, 97 S.Ct. 1305, 1309, quoting from *Rice v. Santa Fe Elevator Corp.* 331 U.S. 218, 230, 67 S.Ct. 1146, 1152 (1947), "we start with the assumption that the historic police powers of the State were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."

exists, then a second question of whether the administrator's action has exceeded the scope of his delegated authority must be answered. *Fidelity Federal Savings & Loan Ass'n. v. De la Cuesta*, 458 U.S. 141, 153-154, 102 S.Ct. 3014, 3022-23 (1982); *United States v. Shimer*, 367 U.S. 374, 381-383, 81 S.Ct. 1554, *1560* (1961).

II. FEDERAL LAW AND ADMINISTRATIVE HISTORY REVEAL AN INTENT NOT TO PRE-EMPT LOCAL PLASMA LAWS.

An examination of the congressional and administrative plasma laws reveal neither congressional intent nor authorization to pre-empt the area.[3] In fact, the administrator specifically announced that *no* preemption of state or local plasma laws was intended. The Commissioner of the Food and Drug Administration[4] [hereinafter cited as FDA] stated in response to inquiries about the initial plasma regulations:

> Some comments expressed concern that the licensing of Source Plasma (Human) would preempt State and local laws governing plasmapheresis. *These regulations are not intended to usurp the powers of State or local authorities to regulate plasmapheresis procedures in their localities.* Rather, the intention is to assure the safety, purity and potency of their biological product when it is shipped in interstate commerce pursuant to Section 351 of the Public Health Service Act. 38 Fed. Reg. 19365

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[3]*See*, 21 U.S.C. §§321 *et seq.*; 42 U.S.C. §§262 *et seq.*; 21 C.F.R. §600. 3-680.26; (JA 54-55).

[4]The Commissioner of the FDA has authority from the Secretary of the Department of Health and Human Services to promulgate regulations under 21 C.F.R. §5.10. Congress gave the Secretary the authority to regulate blood and blood products in 42 U.S.C. §§262 *et seq.* and 21 U.S.C. §§321 *et seq.*

(1973) [Emphasis supplied].[5] Therefore, the initial and primary test under *De la Cuesta* for determining whether federal regulations pre-empt local laws, that is, whether the administrator meant to do so, has not been satisfied.

Moreover, even if this statement of express intent *not* to pre-empt is discounted, no implicit pre-emption by the FDA can be found either.

The "National Blood Policy", which the Eleventh Circuit Court of Appeals cited as evidence of the need for uniformity and federal dominance in the field of plasmapheresis, specifically excludes any application of the policy to commercial plasmapheresis.[6] Moreover, that National Blood Policy was intended to involve" . . . *all relevant public* and private *sectors and Federal Government agencies* in a *cooperative* effort to provide the best attainable blood services." *Id.* at 32703 [Emphasis supplied]. In commenting upon an alternative plan suggested by HEW Task Force on Blood Banking[7] for the implementation of the policy, the Acting Assistant Secretary criticized the plan for not acknowledging:

> the actual and potential role of duly constituted authority, such as *State Departments of Health*, in the process of designating regional programs. This is a significant omission, in light of the rather major role played by the Departments of Health in several states, and, *particularly the future role that some Departments of Health will certainly play* in the course of regionalizing their respective State's blood banking facilities. *Id.* [Emphasis supplied]. The Department intended that the policy take "due regard for the role of *the county medical society*, among others in the process of a regionalization of blood banking activities." *Id.* [Emphasis supplied].

In line with this "cooperative" effort taking due regard for local input, the Federal Register contains one reference to state regulation in the area of blood and blood components, implicitly recognizing a dual system of federal and local regulation.[8] Further, FDA representatives testified at trial that the enforcement of the County legislation would not conflict with their duties under the federal regulations and would, in fact, be helpful.[9]

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[5]The County did not have the opporunity to direct the Eleventh Circuit to this citation prior to its decision. The court denied the County the opportunity to respond to the issue of preemption which was raised initially by an *amicus* brief filed two weeks after the submission of the final briefs by the parties. (JSA 43-47, 22-26)

[6]The Acting Assistant Secretary of Health stated as follows: "Although this comprehensive policy accelerates the evolution of an all-voluntary supply of blood and blood components, *it leaves untouched*, for the time being, the commercial acquisition of plasma and the preparation and marketing of plasma derivatives, and the commercial acquisition of blood for preparation of diagnostic reagents." 39 Fed. Reg. 32702 (1974) [Emphasis supplied].

[7]Two members of that Task Force, Dr. Paul Schmidt and Dr. Frank Coleman testified as experts in the field of plasmapheresis in favor of the County's plasma laws at trial. (TR 177-208)

[8]"Approximately ten states have inspection or licensing provisions with respect to the collection and processing of blood and blood components. The Commissioner finds these programs are inadequate to keep blood containing hepatitis virus from the channels of interstate commerce." 39 Fed. Reg. 18614-5 (1974).

[9]Herbert W. Smith, an FDA Inspector based in Tampa, testified that local County inspections would not interfere with or hinder his job. (TR 215-216) Edward R. Atkins, Director of Compliance for the FDA District Office in Orlando, testified that the enforcement by the county of their regulations would not cause any difficulties for his office and that "any additional inspection of these [plasma] firms would be helpful." (TR 224-225)

Finally, an examination of the congressional and administrative history reveals a different emphasis in the federal legislation than that in the local regulations. The purpose of the local regulations is to protect the health of the people of Hillsborough County.[10] The federal legislation, rather than basing its jurisdiction in local health issues, "rests upon the constitutional power resident in Congress to regulate interstate commerce. [citation omitted]." *United States v. Walsh*, 331 U.S. 432, 434, 67 S.Ct. 1283, 1284 (1941).[11]

In August of 1972, the FDA took over blood regulatory activities from the National Institutes of Health, 37 Fed. Reg. 12865 (1972), and promulgated comprehensive plasma regulations. 37 Fed. Reg. 17419 (1972).[12]

As an adjunct to those plasma regulations and to "insure there is a continued healthy donor population to serve as a source of plasma," 37 Fed. Reg. 17420 (1972), the FDA included regulations designed to protect plasma vendors. Although the federal government has, thereafter, announced that its regulations are designed both to protect the product and the source, its jurisdiction to regulate vendor protection has always been based upon its primary concern for the product as it passes from state to state.[13]

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[10](JA 24,25)

[11]The Court was speaking specifically of the Federal Food, Drug and Cosmetic Act, [21 U.S.C. §§301 *et seq.*].

[12]The federal government began regulating the sale of blood and blood products as early as 1902 under the "Virus-Toxin Law" which was recodified in 1944 in the Public Service Health Act, 42 U.S.C. 262, 263 and which was specifically amended to add the words "blood and blood components or derivatives" in 1970 at 42 U.S.C. 351, 352. Division of Biologics Standards, National Institutes of Health, U.S. Dept. of Health, Education and Welfare, *Legislative History of the Regulation of Biological Products*, (June 1971).

[13]*See United States v. Walsh, supra*. Other comments by officials in the Federal Register which illustrate that the primary federal con-

III. LOCAL PLASMA LAWS DO NOT CONFLICT WITH FEDERAL LAWS BUT SUPPLEMENT AND REINFORCE THEM:

While the initial concern of the federal government is the product, that of Hillsborough County is the *source* of that product—its people. County officials found that the gathering of medical data on, and the identification of, plasma vendors promotes the public health. (JA 24-25)

The testimony at trial established four provisions for the protection of plasma vendors which are not found in

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13 Con't.

cern is to ensure a safe and plentiful product in interstate commerce include the following:

> Human blood is a significant source of hepatitis and other communicable diseases, and if not collected, processed and distributed under appropriate standards, *may contaminate the product*. Approximately ten states have inspection or licensing provisions with respect to the collection and processing of blood and blood components. The Commissioner finds these programs are inadequate *to keep blood containing hepatitis virus from the channels of interstate commerce*. 37 Fed. Reg. 18614-18615 (1974) [Emphasis supplied]; and,
>
> Certain aspects of the donor protection requirements *directly affect the safety, purity and potency of the plasma*, such as those provisions concerning donor suitability that are designed to assure that plasma is free of disease-carrying agents. In an indirect but no less important manner, the requirements of donor protection *assure* as the Commissioner stated more than 3 years ago that there will be a *continuous and healthy donor population*. Finally, the Commissioner believes that it is an *inherent obligation of government to assure that where standards are established for products, the public health factors that are integral to the product must be considered and protected*. Such action is necessary and proper in the exercise of the underlying authority. 41 Fed. Reg. 10762 (1976) [Emphasis supplied].

the federal plasma regulations and which serve to protect local interests. These additional protections as as follows: 1) the establishment of a county-wide plasma vendor registration system; 2) the requirement that prospective plasma vendors submit to a test for hepatitis prior to their plasma being drawn; 3) the provision for enforcement of the local legislation in Hillsborough County by the County Health Department; 4) the requirement that prospective vendors undergo a breath analysis so as to determine the alcohol content of their blood.[14]

III.(a) VENDOR REGISTRATION

The purpose of a county-wide plasma vendor registration system is to prevent the excessive bleeding of vendors beyond the levels and frequency set by the federal regulations. The vendors are able to overbleed themselves, and thus jeopardize their health, through the practice of cross-bleeding whereby they go from plasma center to plasma center selling their plasma at each center they visit. Although the federal regulations set limits for the frequency and levels beyond which vendors cannot be bled and require each individual center to maintain records on each vendor to protect against over-bleeding at any one center, those regulations do not require that these centers exchange bleeding lists with one another and do not otherwise protect against excessive cross-bleeding which takes place at different centers (TR 63, 165-166, 183, 215, 224). The centers, likewise, do not exchange such information on a

[14]The breathalyzer requirement was the only portion of the local legislation which the trial court held invalid. Judge Castagna ruled that although this portion of the local legislation was not preempted, it imposed an impermissible burden on interstate commerce (JA 46-47). The County's cross-appeal on this issue was not ruled upon by the Eleventh Circuit.

regular basis. Mili Lamas, Automated's Vice President, stated that the employees at TPC "don't have a way of knowing whether he [the vendor] has donated at another center before or not." (TR 63). While Ms. Lamas testified that the employees at TPC "voluntarily" check with another center in Hillsborough County if they have a problem identifying a prospective vendor, AML stipulated that TPC doesn't exchange donor lists with any other center in Hillsborough County. (R 38, p. 7, para. 27) Further, even if TPC were to compare its records at another center in Hillsborough County on a regular basis, neither TPC nor any other plasma center would be under a duty to engage in or continue such an exchange of information. Thus, Hillsborough County's only assurance of protection against excessive over-bleeding or cross-bleeding lies in the local legislation.[15]

III.(b) PRE-TESTING FOR HEPATITIS
i) REQUIREMENTS IN ADDITION TO FEDERAL REGULATIONS

The local legislation also requires that prospective vendors have a negative hepatitis test result before they can receive a vendor identification card from the County Health

[15]The Eleventh Circuit's lack of understanding of the difference between the federal single-center over-bleeding enforcement provisions and the County's multi-center cross-bleeding provision is obvious from the statement in its opinion that "TPC can deter any attempted donation" which would result in a health risk to the vendor or in a violation of the federal bleeding limits through the use of its "permanent donor record file" which contains bleed information only at TPC. (JA 51-52). Of course, such a file would be quite effective at eliminating excessive cross-bleeding if the vendor was only allowed to be bled by one center which followed TPC's practices. This is the goal of the center-specific identification card provision in the County's regulations.

Department (TR 150). This requirement is in contrast with the federal regulations which require plasma center employees to draw a blood sample from a vendor after they have already bled that vendor. The sample is then sent off to a lab for testing while the drawn plasma is kept at the center, 21 C.F.R. §610.40. (TR 66).

The local legislation would prohibit, absent written authorization as provided for in 21 C.F.R. §640.75, any prospective plasma vendor with a history of viral hepatitis or contact with hepatitis from obtaining a County Vendor Identification Card, selling his or her plasma and thereby exposing other vendors, center personnel as well as any other people present in the center, to the danger of hepatitis contagion.[16] Automated emphasizes the use of sterile plastic bags and tubing as though this would eliminate the risk of hepatitis. Even Ms. Lamas, however, admitted at trial that a plasma bag may break or that plasma may spill during the plasmapheresis procedure (TR 65-66). Additionally, Dr. Kwalick testified that more persons potentially can be contaminated by hepatitis-positive plasma under the federal regulations than under the local legislation (TR 150-151). This protection is particularly necessary for *paid* plasma vendors such as those in Hillsborough County, because paid blood vendors have a much higher incidence of hepatitis infection than volunteer blood donors. (JA 45, TR 155-156).[17]

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[16]The Associate Commissioner for Compliance with HEW, Sam D. Fine, acknowledged the government's concern with "thousands of technicians" who handle plasma infected with hepatitis B antigen while unaware of that infection. 39 Fed. Reg. 26162 (1974). Although this comment was listed as a rationale for the labeling requirements of the federal regulations, it supports the County regulations requiring the testing of the plasma vendor as well.

[17]*See, also,* J. Walsh, P. Schmidt *et al., Post Transfusion Hepatitis After Open-Heart Operations,* 211 JOURNAL OF THE AMERICAN MEDICAL

III.(b)(ii) THE SOLICITOR GENERAL'S ASSERTION THAT THIS PROVISION CONFLICTS WITH FEDERAL LAW IS UNFOUNDED

The Solicitor General as Amicus Curiae to the Court has stated that the County's requirement that a vendor be in "good health" conflicts with the federal regulations which allow for the bleeding of individuals with hepatitis B surface antigen, the source for hepatitis vaccine. 21 C.F.R. §640.75. However, this conflict is illusory for several reasons.

First, the County's requirement for the good health of a vendor are the same as those requirements in the federal regulations (JA 27, Section D) and thus does not conflict with them or require less or more than they do. Secondly, the County incorporates by reference 21 C.F.R. §640.75 which the Solicitor General cites as the federal regulation allowing for the bleeding of individuals who are not in good health for the express purpose of obtaining plasma for production of hepatitis vaccine and diagnostic products. Thus, the provision allowing a plasma center, upon written approval of the Director of the Bureau of Biologics, to collect plasma from those not eligible for a good health certificate would be upheld and enforced by the County. Thirdly, those who have a history of viral hepatitis or who may be infected with hepatitis, which are those not eligible to receive a vendor card from the County, are not the same as those vendors who carry the hepatitis B surface antigen which is necessary to produce the hepatitis vaccine. In a

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17 Con't.
ASSOC. 261-265 (Jan. 12, 1970) (wherein the authors state that "the chance of hepatitis developing is higher among patients given blood obtained from our commercial blood sources than among patients given blood supplied by local volunteer donors.") *Id.* at 264.

journal published by the federal government, the Committee on Viral Hepatitis found that "[a] chronic carrier of the antigen may or may not have demonstrable evidence of related liver disease." The Committee On Viral Hepatitis, U.S. Department of Health, Education and Welfare, *The Public Health Implications Of Hepatitis B Antigen In Human Blood*, 23 MORBIDITY AND MORTALITY 125 (1974).[18]

Finally, the supposed conflict asserted by the Solicitor General was never presented to the trier of fact for a determination of whether such a conflict does exist. As this Court has stated, it will not assume in advance that "a State will so construe its law as to bring it into conflict with the federal constitution or an act of Congress." *Allen-Bradley Local v. Wisconsin Employment Relations Board*, 315 U.S. 740, 746, 62 S.Ct. 820, 824 (1942). In fact, a representative of AML testified at trial that a vendor whose plasma has tested positively for hepatitis is told if he returns to the center that "he no longer can donate plasma nor whole blood at our facility or anywhere else, and he is permanently rejected as a donor." (TR 36-37). In addition, as noted by the Eleventh Circuit, TPC destroys any unit of plasma where a sample of it is found to be contaminated with hepatitis (JA 51). Hepatitis contaminated plasma obtained in Hillsborough County under the federal regulations is not used. Accordingly, no conflict between the two regulations is apparent and, in light of the reasons listed above, cannot be

[18]*See, also,* P. Holland, *et al., Viral Hepatitis Markers in Soviet and American Blood Donors*, 20 TRANSFUSION 504 (Jan.-Feb. 1980) (wherein 1.5% of vendors in Tampa with no history of viral hepatitis were carriers of the antigen), LIVER AND BILIARY DISEASE 661 (R. Wright *et al.* ed. 1979) ("It can be argued that a carrier of HB_5Ag [the antigen] should be described as one who is asymptomatic and who has no histological evidence of liver disease. In such individuals, histological evidence of hepatitis may not be present, ...").

presumed to exist by this Court prior to the County actually enforcing its regulations.[19]

III.(c) LOCAL INSPECTION AND ENFORCEMENT

The local legislation also provides for the enforcement of its provisions as well as the provisions of the incorporated federal regulations by the Hillsborough County Health Department. The two FDA inspectors based in Tampa and charged with the enforcement of the federal plasma regulations must cover an area including nine (9) counties and must enforce all of the FDA regulations in that area (TR 210). Although these inspectors are assisted at times by other FDA personnel, no one is regularly at the local office to answer any incoming calls (TR 210-211).

Additionally, Dr. Schmidt testified that the Bureau of biologics, the division responsible for enforcement of federal plasma regulations, was to be merged with the Bureau of Drugs, leaving a smaller group with more responsibilities (TR 188). He also stated that even prior to the merger, federal inspectors have been to his blood bank only once in the last thirty-nine (39) months though they were required to inspect once a year (TR 187).[20]

III.(d) BREATHALYZER TEST

Finally, the local legislation requires that a prospective vendor undergo a breath analysis prior to his or her plasma being drawn so that the blood alcohol level can be deter-

[19]Respondent filed its lawsuit against the County approximately one month after the local legislation was passed by the Board of County Commissioners and the County has not enforced it pending an ultimate judicial decision on the claims raised in that lawsuit.

[20]As the Eleventh Circuit noted, (JA 58), inspections by the FDA were cut from one every year to one every *two* years as of July 7, 1983. 48 Fed. Reg. 26313 (1983).

mined (JA 28, 33, TR 184-185,215). The results of the test must not show more than 0.07 percent alcoholic content in the vendor's blood (JA 28, 33). Each plasma center is required to maintain upon its premises the equipment and personnel required for the purpose of performing the breath analysis (JA 28, 33).

These provisions would ensure that the vendor be capable of giving truly informed consent prior to submitting to the risks of the plasmapheresis procedure (TR 149-150). Additionally, these provisions are intended to ensure that each vendor will have the capacity to assist in the return of the necessary blood cells following the withdrawal of his or her plasma (TR 149-150)[21] and that each vendor will give an accurate medical history (TR 149-150, 207-208). As Dr. Coleman testified, an intoxicated vendor is totally unreliable in relating his or her medical history to center personnel (TR 207-208).

These protections provided by this breathalyzer requirement are not otherwise provided for by the federal regulations. The federal regulations require only that center personnel "interview" a prospective vendor. On the basis of this interview alone, the "interviewer" is expected to be able to ascertain the sobriety or intoxication level of a prospective vendor. 21 C.F.R. §640.63(d) (TR 183-184). The federal regulations do not contain any requirements as to the qualifications of that interviewer. 21 C.F.R. §640.63.

[21] As noted by the FDA, returning to a vendor the red blood cells of another vendor "can lead to a hemolytic transfusion reaction and death." 30 Fed. Reg. 26161 (1974). The Court need only consult local newspaper to find that these reactions occur even with the federal regulations in place. *See, e.g.*, Kalfus, *Plasma Center Puts Wrong Blood Back in Man*, TAMPA TRIBUNE, Feb. 8, 1985, at 1-B; ST. PETERSBURG TIMES, Feb. 10, 1985, at 17-B; MIAMI HERALD-TRIBUNE, Feb. 9, 1985, at 2-B.

Thus this interviewer need not be a physician nor even an employee possessing any medical training.

Dr. Schmidt, an expert in the plasmapheresis field, testified that the federal regulations do not provide "a valid way to exclude some people who might be under the influence of alcohol." (TR 184). Dr. Coleman, also a plasmapheresis expert, testified that the "subjective observation of somebody in the center" is not an adequate way to measure vendor intoxication (TR 205). Thus, the County presented unrefuted evidence at trial in support of its position that the objective breathalyzer requirement of the local legislation affords valuable protection to the prospective vendor which is not available in the subjective evaluation mandated by the federal regulations but which fulfills the same purpose as and does not conflict with those regulations.

IV. THE ELEVENTH CIRCUIT'S RULING THAT FEDERAL REGULATIONS IMPLICITLY PRE-EMPT THE LOCAL LEGISLATION IS INCORRECT.

The local legislation is neither explicitly nor implicitly pre-empted by the federal plasma regulations which it supplements and reinforces. The Eleventh Circuit's ruling that the local legislation is implicitly pre-empted because it conflicts with the federal scheme which is pervasive and dominant is contradicted by the two regulatory schemes themselves, the administrative history and the record. As noted earlier, the Commissioner of the FDA stated an express intent *not* to pre-empt and FDA representatives testified that no practical conflicts would arise in enforcing the two regulatory schemes. In light of this, the mere comprehensiveness of the federal scheme cannot serve to displace the local law. Moreover, the federal regulations *do* leave

room for supplementation in the area of vendor protection, as Dr. Schmidt and Dr. Coleman testified. The county has moved in to fill that void. Comprehensiveness cannot imply pre-emption particularly where as here, the federal government had to promulgate regulations sufficient to govern in states without any regulatory activity.[22] Conversly, if Congress or the FDA had intended to pre-empt this area, a clear intent to do so is necessary inasmuch as some states did have regulations in existence when the Commissioner declared the federal regulations.[23]

The Eleventh Circuit's opinion that the federal interest in plasma is dominant over any local interest because the federal regulations establish a uniform national blood policy is invalid for two reasons. First of all, that national policy does not encompass the commercial collection and manufacture of plasma, as noted earlier.[24] Secondly, the federal uniform standards constitute only a minimum level of public health protection to ensure an uncontaminated product beyond which local governments may impose additional reasonable standards to protect that product's

[22]*See, e.g., New York State Dept. of Social Services v. Dublino,* 413 U.S. 405, 415, 93 S.Ct. 2507, 2515 (1973), "This would be especially the case when the federal work incentive provisions had to be sufficiently comprehensive to authorize and govern programs in states which had no welfare work requirements of their own as well as cooperatively in states with such requirements." As cited earlier, the Commissioner of the FDA acknowledged that only ten states had plasma inspection or licensing provisions when he promulgated the federal regulations. *See, pp.9, 10, nn. 8 & 13, supra.*

[23]*See, id.* at 414, 93 S.Ct. 2513, "Moreover, at the time of the passage of WIN in 1967, 21 states already had initiated welfare work requirements as a condition of AFDC eligibility. [footnote omitted] If Congress had intended to pre-empt state plans and efforts . . . , such intentions would in all likelihood have been expressed in direct and unambiguous language."

[24]*See,* p.8, n.6, *supra.*

source.[25] As a member of the federal government's own advisory commission testified, additional standards had been suggested to the federal officials, who had declined to include them in their regulations.[26]

The ruling by the Eleventh Circuit that the local legislation is implicitly pre-empted by the federal regulations is not supported by the law or the record and misapprehends the intent of a cooperative system based upon minimum federal standards supplemented and enforced by local governments when the need arises, as it has in Hillsborough County , Florida. The local legislation should be upheld by this court.

[25]*Cf. Florida Lime and Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 83 S. Ct. 1210 (1963) where federal regulation over the picking of avocados at the source did not prohibit California from passing laws governing its acceptance of the product in the marketplace.

[26]Dr. Paul J. Schmidt testified that the Commission "made certain recommendations as to what could be done, and not all of those recommendations are in the federal regulations. The federal government chose not to accept all of those opinions." (TR 183-185) He also stated that the "specific point of the identification and the regional registries was addressed and recommended. The federal regulatory people chose to ignore that when they wrote their regulations." *Id.*

CONCLUSION

The County requests that this Court reverse the holding of the Eleventh Circuit and enter a ruling that Hillsborough County Ordinances No. 80-11, No. 80-12 and the Rules and Regulations promulgated thereunder are not pre-empted by congressional law found at U.S.C. §§ 321 *et seq.* and 42 U.S.C. §§ 262 *et seq.* nor by the administrative regulations found at 21 C.F.R. §§ 600.3-680.26 and, further, that there is no present conflict between the local and federal scheme. In the alternative, the County requests that this Court find that no pre-emption exists and remand the case back for a determination of whether any conflict between the federal and local regulations exists.

Respectfully Submitted,

JOE HORN MOUNT
Hillsborough County Attorney
P.O. Box 1110
Tampa, Florida 33601
(813) 272-5670

EMELINE C. ACTON
Assistant Hillsborough County Attorney
P.O. Box 1110
Tampa, Florida 33601
(813) 272-5670

CERTIFICATE OF SERVICE

All parties required to be served have been re-served by depositing on this 2nd day of March, 1985, three printed copies of this document with an overnight delivery service, addressed to counsel of record at his or her post office address as follows:

Larry A. Stumpf, Esq.
Finley, Kumble, Wagner,
Heine, Underberg, Manley
& Casey
Counsel for Appellee
Automated Medical
Laboratories, Inc.
Suite 1000 Flagship Center
777 Brickell Avenue
Miami, Florida 33131

Paul Larkin, Esq.
Counsel for Amicus
United States Government
Dept. of Justice
Solicitor General's Office
10th and Constitution Ave.
Room 5634
Washington, D.C. 20004

Joyce Holmes Benjamin, Esq.
Counsel for Amicus
The Academy for State and
Local Government
The State & Local Legal Center,
Suite 349
444 North Capital Street, N.W.
Washington, D.C. 20001

Richard Landfield, Esq.
Landfield, Becker & Green
Counsel for Amicus
American Blood Resources
Assoc.
1220 Nineteenth Street, N.W.
Suite 205
Washington, D.C. 20036

JOE HORN MOUNT
Counsel of Record
Hillsborough County Attorney
Member, United States
Supreme Court Bar
Post Office Box 1110
Tampa, Florida 33601
(813) 272-5670